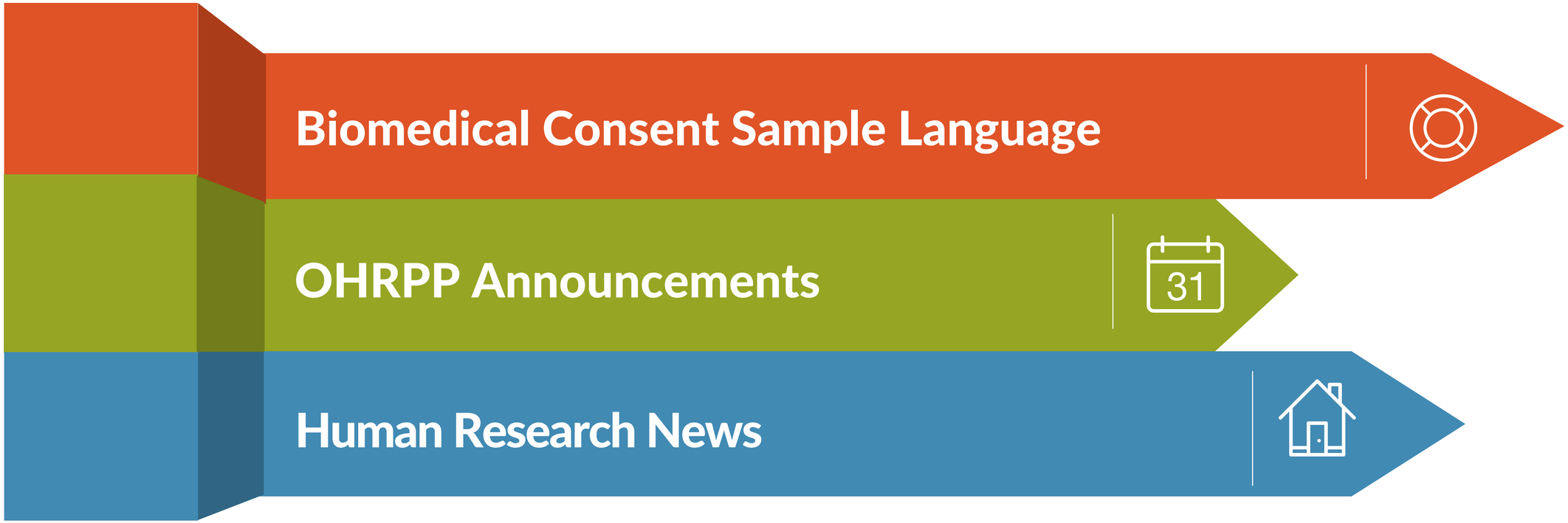
UCLA Research Administration

OHRPP Updates: Biomedical Consent Sample Language

October 13, 2022

OHRPP Updates



Biomedical Consent Standards and Sample Language

A revised version of the Biomedical Research Consent Form Standards and Sample Language was uploaded this week to the OHRPP website.

- Because recommended language can and does change, we strongly encourage researchers to start with the current template (and not modify previously approved consent forms from previous studies). ***Why?***
  - ✓ Regulatory/Policy landscape may have changed
  - ✓ Verbiage may have been improved for greater clarity/flexibility for researchers
  - ✓ This will prevent artifacts from other studies (such as procedures that aren't being conducted in the current research being left in from the previous research) slowing down IRB review

Biomedical Consent Changes

Clarification of ***research information included in health record*** and access to information:

"This consent form and some details of your study participation will be noted in your UCLA Health record. If you do not currently have a UCLA Health record, one will be developed for you. People involved with your medical care and insurance at UCLA or other organizations may become aware of these details. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your UCLA Health record until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records."

~~"You may request access to your records at any time, however receiving certain records that may unblind you to which arm of the study you are assigned will result in you having to be removed from the study."~~

Biomedical Consent Changes

Clarification of ***future use of data and specimens collected for research***:

"Your data and/or specimens, including de-identified data and/or specimens may be kept for use in future research, including research that is not currently known. If you do not want your data and/or specimens to be used for future research you should not participate in this study."

(blue text added)

Biomedical Consent Changes

The verbiage for one option for disposition of specimens/data has been simplified/broadened for ***disclosure of Moore vs. Regents of the University of California Supreme Court of California decision***:

"Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them."

~~**"If specimens will be kept by UCLA:**~~

~~**Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the University of California. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.**~~

~~**If specimens will be provided to an outside entity, such as the study sponsor or national group:**~~

~~Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will be provided to [the Sponsor of this study (company name optional) or the name of the national group). These specimens will not include information that identifies you directly. Once you provide the specimens you will not have access to them. The specimens will be used for research and such use may result in discoveries that could become the basis for new products or therapeutic agents. In some instances, these discoveries may be of potential commercial value. You will not receive any money or other benefits derived from such a product."~~

Learn at Lunch

“Regulatory Compliance and clinicaltrials.gov”

October 26, 2022 at noon

Presenter: ***Elaine Cooperstein***, Clinical Trials Government Liaison, UCLA Office of Regulatory Affairs, CTSI.

Register for the zoom link

OHRPP Office Hours

- OHRPP Quality Improvement Unit staff are hosting ***half-hour open Q/A sessions every other week*** to answer your questions

- *Upcoming sessions*
  - Tuesday, October 25, 2022 8:30am
  - Tuesday, November 8, 2022 8:30am

Register once and you can join any session.

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Contact

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